

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.*)) No. 1:19-cv-04676-PAE
Plaintiffs,) (rel. 1:19-cv-05433-PAE; 1:19-cv-
v.) 05435-PAE)
)
UNITED STATES DEPARTMENT OF) DEFENDANTS' CONSOLIDATED
HEALTH AND HUMAN SERVICES;) REPLY IN SUPPORT OF
ALEX M. AZAR II, *in his official capacity as*) DEFENDANTS' MOTION TO
Secretary of the United States Department of) DISMISS OR, IN THE
Health and Human Services; and UNITED) ALTERNATIVE, MOTION FOR
STATES OF AMERICA,) SUMMARY JUDGMENT, AND IN
Defendants.) OPPOSITION TO PLAINTIFFS'
) MOTIONS FOR SUMMARY
) JUDGMENT
)
)
)
PLANNED PARENTHOOD FEDERATION) No. 1:19-cv-05433-PAE
OF AMERICA, INC.; and PLANNED) (rel. 1:19-cv-04676-PAE; 1:19-cv-
PARENTHOOD OF NORTHERN NEW) 05435-PAE)
ENGLAND, INC.,)
)
Plaintiffs,)
)
v.)
)
ALEX M. AZAR II, *in his official capacity as*)
Secretary, United States Department of)
Health and Human Services; UNITED)
STATES DEPARTMENT OF HEALTH)
AND HUMAN SERVICES; ROGER)
SEVERINO, *in his official capacity as*)
Director, Office for Civil Rights, United)
States Department of Health and Human)
Services; and OFFICE FOR CIVIL RIGHTS,)
United States Department of Health and)
Human Services,)
)
Defendants.)
)

NATIONAL FAMILY PLANNING AND)
REPRODUCTIVE HEALTH) No. 1:19-cv-05435-PAE
ASSOCIATION; and PUBLIC HEALTH) (rel. 1:19-cv-04676-PAE; 1:19-cv-05433-
SOLUTIONS,) PAE)
)
Plaintiffs,)
)
v.)
)
ALEX M. AZAR II, in his official capacity as)
Secretary of the U.S. Department of Health)
and Human Services; U.S. DEPARTMENT)
OF HEALTH AND HUMAN SERVICES;)
ROGER SEVERINO, in his official capacity)
as Director of the Office for Civil Rights of)
the U.S. Department of Health and Human)
Services; OFFICE FOR CIVIL RIGHTS of)
the U.S. Department of Health and Human)
Services,)
)
Defendants.)
)

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INTRODUCTION

Defendants respectfully ask that the Court enter summary judgment in their favor. Plaintiffs' memoranda are long on hyperbole, but despite well over one hundred pages of briefing, Plaintiffs at no point articulate how they believe the challenged Rule meaningfully differs from the Federal Conscience Statutes. That is because—far from constituting a sea change, as Plaintiffs argue—the Rule merely implements and clarifies those important preexisting conscience protections enacted by Congress. Indeed, Plaintiffs confirm in their most recent briefs that they do not, in fact, challenge the underlying Federal Conscience Statutes. And they acknowledge that Defendants have the authority to determine whether a recipient of federal funds administered by the Department of Health and Human Services (HHS) is in compliance with those statutes. Taken together, these concessions are fatal to Plaintiffs' claims against the Rule. At bottom, because the Federal Conscience Statutes are lawful conditions on the receipt of federal funding, and because the Rule faithfully and reasonably implements those longstanding conditions as to funds HHS administers, Plaintiffs' suit fails.

Plaintiffs' specific arguments fail for other reasons, too. The main thrust of Plaintiffs' Administrative Procedure Act (APA) challenge is the claim that the Rule exceeds Defendants' statutory authority. But Plaintiffs' argument is belied by the explicit delegations of authority in certain of the Federal Conscience Statutes and other statutes identified in the preamble to the Rule. Plaintiffs' attack on several of the Rule's definitions fares no better because the definitions are consistent with the plain text of the Statutes and the dictionary meanings of the relevant terms. At the very least, the Rule's definitions are entitled to *Chevron* deference and are reasonable. Contrary to Plaintiffs' claim, the Rule is also entirely consistent with the provisions scattered throughout the United States Code that Plaintiffs cite. And, in promulgating the Rule, Defendants engaged in

reasoned decisionmaking, thoroughly considering the issues raised in the comments and providing thoughtful explanations in response.

Plaintiffs' constitutional claims likewise fail. As an initial matter, they are not ripe. Although Plaintiffs insist that the loss of "billions of dollars in federal funds" is imminent, that is not the case. *See New York v. HHS*, 19-CV-04676-PAE, Mem. of Law in Supp. of Pls.' Cross-Mot. Summ. J., in Opp'n to Defs.' Mot. to Dismiss or for Summ. J., and Reply in Supp. of Pls.' Mot. Prelim. Inj. (NY Opp'n) at 1, ECF No. 182. Several speculative events would need to take place before Plaintiffs could potentially lose federal funding for failure to comply with the Rule. There is simply no immediate risk of the withdrawal of funds that would make Plaintiffs' Spending Clause and Establishment Clause claims ripe. In any event, those claims fail on the merits. The funding conditions Plaintiffs challenge flow from the Federal Conscience Statutes themselves, which—because Plaintiffs do not challenge those Statutes—is fatal to Plaintiffs' Spending Clause claim. The Rule also does not "establish" religion in any way. It protects religious beliefs only where the underlying statutes protect religious beliefs. Moreover, most of the protections provided by the Rule (and the underlying Federal Conscience Statutes) address objections to certain services regardless of whether those objections are based on religious or non-religious beliefs.¹

For all these reasons, the Court should enter judgment in favor of Defendants. However, even if the Court were to find some aspect of the Rule unlawful—which it should not—the Court

¹ In their Complaints, Planned Parenthood and the National Family Planning Reproductive Health Association (NFPRHA) alleged that the Rule is unconstitutionally vague and violates the Fifth Amendment. *See Planned Parenthood Fed'n of America v. Azar*, No. 1:19-cv-05433, Compl. ¶¶ 148–52; *Nat'l Family Planning and Reproductive Health Ass'n v. Azar*, No. 1:19-cv-05435, Compl. ¶¶ 154, 156–67. Those Plaintiffs now indicate that they "no longer seek relief on these claims." Planned Parenthood Mem. Supp. Pls.' Cross-Mot. Summ. J., Opp. Defs.' Mot. Dismiss or Summ. J., and Reply Supp. Pls.' Mot. Prelim. Inj. (PP Opp'n) at 53 n.39, ECF No. 184. The Court should therefore enter summary judgment in Defendants' favor on those counts.

would be obligated by the Rule’s severability clause to sever that portion from the remainder of the Rule rather than vacate the Rule in its entirety. Any relief, moreover, should be limited to the parties before the Court and not extend nationwide.

ARGUMENT

I. The Rule Fits Comfortably Within HHS’s Authority.

Contrary to Plaintiffs’ view, the Rule is a product of HHS’s longstanding authority to ensure that recipients of its federal awards comply with federal law, including the Federal Conscience Statutes.

As Defendants explained in their opening brief, the Rule’s enforcement authority section reflects longstanding—and unchallenged—law concerning HHS’s authority to monitor and enforce compliance with federal awards that it issues. *See* Defs.’ Consol. Mem. Supp. Defs.’ Mot. Dismiss or, in the Alt., Mot. Summ J., Opp. Pls.’ Mots. Prelim. Injs. 23–26 (Defs.’ Mem.), ECF No. 148. Pursuant to various housekeeping and other statutes, *see* 5 U.S.C. § 301, 40 U.S.C. § 121(c), 10 U.S.C. ch. 137, and 51 U.S.C. § 20113, HHS has promulgated grants and contracts regulations that correspond to and or supplement the UAR and FAR (known as the HHS UAR and HHSAR), which among other things govern the enforcement of conditions in federal awards. Under these regulations, recipients of HHS’s federal awards are required to comply “with U.S. statutory and public policy requirements,” 45 C.F.R. § 75.300(a), which include the Federal Conscience Statutes. HHS may, and in some cases must, audit recipients for compliance with this and other conditions. *See* 45 C.F.R. §§ 75.500–75.520. And if a recipient does not comply with a federal award’s requirements, HHS may impose additional conditions or take further action, including to “[w]holly or partly suspend . . . or terminate the Federal award.” 45 C.F.R. § 75.371. Further, under the 2011 Rule, HHS explicitly states that it enforces the Church, Coats-Snowe, and Weldon Amendments using these procedures. *See* 45 C.F.R. § 88.2 (“OCR will coordinate the

handling of complaints [based on the Church, Coats-Snowe, and Weldon Amendments] with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding.”). Plaintiffs do not object to these procedures, *see* Planned Parenthood Mem. Supp. Pls.’ Cross-Mot. Summ. J., Opp’n to Defs.’ Mot. Dismiss or Summ. J., & Reply Supp. Pls.’ Mot. Prelim. Inj. (PP Opp’n) 16, ECF No. 184, nor could they. The Federal Conscience Statutes instruct HHS to issue federal funds with certain conditions and instruct recipients to comply with those conditions. Were HHS unable to invoke longstanding federal award enforcement procedures to ensure such compliance, recipients could violate the terms of their awards with impunity. This could not have been Congress’s intent when it enacted the Federal Conscience and housekeeping statutes.

In addition to this longstanding authority, several statutory provisions explicitly grant HHS sufficient regulatory authority here. *See* 42 U.S.C. §§ 1302, 18023, 18113, 18041, 263a, 1315a. And, as discussed in the definitions section *infra*, the Federal Conscience Statutes implicitly grant HHS the authority to administer them.

Despite the clear alignment between the current enforcement regulatory regime and the 2019 Rule, Plaintiffs imagine contradictions. First, they claim that certain HHS “pronouncements” indicate that the Rule is broader than the UAR. *See* PP Opp’n 12. But, as discussed above, the Rule does not supplant the UAR. Contrary to Plaintiffs’ suggestion, it remains the case that the remedies listed at 45 C.F.R. § 75.371 may only be pursued “[i]f the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions.” Plaintiffs also state, without support, that “UAR remedies focus on ‘the cost of the activity or action not in compliance, or the specific ‘Federal award’ involved.’” PP Opp’n 14. But the section of the HHS UAR that Plaintiffs cite is not so limited. In fact, that section permits HHS to “terminate

the Federal award,” to “[i]nitiate suspension or debarment proceedings,” to “[w]ithhold further Federal awards for the project or program,” and to “[t]ake other remedies that may be legally available.” 45 C.F.R. § 75.371. At any rate, the Rule is clear that “[i]t would be premature and contrary to the history of OCR enforcement to deem [anything in the Rule] as a requirement that OCR terminate all, or even some, funding of all entities found to have committed a violation.” 84 Fed. Reg. at 12,223. “OCR only rarely imposes termination of funding as a penalty for . . . violations” of civil rights laws, and under the Rule, “[w]hat specific remedy is appropriate in the case of a particular violation depends on the facts and circumstances.” *Id.* In sum, the HHS UAR and the statutory authority underlying it continue to apply to federal awards that HHS issues, and the Rule is consistent with that authority.

Plaintiffs also contend that enforcement authority cannot be inferred from the Federal Conscience Statutes. *See* PP Opp’n 14–15. Plaintiffs are correct that Congress has explicitly delegated enforcement authority in some contexts. *See id.* at 15. But the existence of explicit delegations in other parts of the United States Code has no bearing on HHS’s authority to ensure compliance with the Federal Conscience Statutes and this Rule under the enforcement provisions of the HHS UAR or HHSAR. Plaintiffs have not shown that statutes on which they rely, which were enacted in different sessions of Congress and as different public laws, are subject to inter-textual comparison as they would like. *See* Defs.’ Mem. 32–33. As discussed below, in addition to statutes that explicitly authorize HHS to ensure that its grant recipients comply with the conditions found in federal law, the Federal Conscience Statutes implicitly authorize HHS to ensure that recipients of the funds that it disburses and administers comply with those statutes; otherwise, the statutes would be unenforceable and thus meaningless.

II. The Challenged Definitions Are Within HHS’s Statutory Authority.

The challenged definitions in the Rule reflect the unambiguous meaning of the terms in the

Federal Conscience Statutes. At a minimum, they are reasonable interpretations entitled to *Chevron* deference.

A. The Highly Differential Standard Described in Chevron Applies.

Plaintiffs contend that the Rule’s definitions are not entitled to *Chevron* deference because Congress has not delegated authority to HHS to interpret the Federal Conscience Statutes. PP Opp’n 7. But, as explained in Defendants’ opening brief and below, Congress has delegated such authority both explicitly and implicitly. The Court thus should review Plaintiffs’ challenges to the Rule’s definitions under the highly deferential framework set forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

To begin with, several statutes explicitly authorize HHS to issue the Rule, which merely provides public notice of HHS’s process for implementing the requirements of the Federal Conscience Statutes and the interpretations of those Statutes that HHS will employ in that process. A number of statutory provisions provide authority for HHS to issue the Rule, including 42 U.S.C. §§ 1302, 18023, 18113, 18041, 263a, and 1315a. *See* Defs.’ Mem. 25–26; 84 Fed. Reg. at 23,185 (listing statutes). And other statutes that support HHS’s enforcement of federal awards, 5 U.S.C. § 301; 40 U.S.C. § 121(c) (procurement contracts); 42 U.S.C. § 216 (grants), also explicitly delegate such authority. *See* Defs.’ Mem. 24–25. In one conclusory sentence, Plaintiffs contend that the Rule cannot be authorized by the housekeeping statutes because the Rule is too broad. *See* PP Opp’n 9. But the breadth of a regulation has no bearing on whether it is authorized by law. After all, the UAR, FAR, HHS UAR, and HHSAR, which Plaintiffs do not dispute are properly promulgated pursuant to the housekeeping and other statutes, provide far broader authority to enforce conditions on federal awards than the Rule. The housekeeping statutes are “a grant of authority to the agency to regulate its own affairs.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). This is precisely what the Rule does; it provides guidance on how HHS defines key terms

and the procedures it will use to enforce the condition imposed on its federal awards under the Federal Conscience Statutes.

Yet another source of authority is the implicit delegation from the Federal Conscience Statutes themselves. “[A]n ‘administrative implementation of a . . . statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.’” *Id.* at 105 (quoting *Rotimi v. Gonzales*, 473 F.3d 55, 57 (2d Cir. 2007)). Just as Congress may delegate authority to the agency explicitly, “[s]ometimes the legislative delegation to an agency on a particular question is implicit.” *Chevron*, 467 U.S. at 844. Although Plaintiffs focus on whether the Rule is supported by an explicit delegation provision (and it is), implicit delegations are also common: “The power of an administrative agency to administer a congressionally created and funded program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress.” *Morton v. Ruiz*, 415 U.S. 199, 231 (1974). “[I]t can still be apparent from the agency’s generally conferred authority and other statutory circumstances that Congress would expect the agency to be able to speak with the force of law when it addresses ambiguity in the statute or fills a space in the enacted law, even one about which ‘Congress did not actually have an intent’ as to a particular result.” *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001) (quoting *Chevron*, 467 U.S. at 845). To determine whether Congress has implicitly delegated authority, courts consider “the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time.” *Barnhart v. Walton*, 535 U.S. 212, 222 (2002). All of these factors weigh in HHS’s favor.

First, the subject of the Rule is interstitial in nature and necessary to the administration of the Federal Conscience Statutes. In general, the Federal Conscience Statutes direct HHS to issue federal funds contingent on recipients complying with the Statutes' conditions. *See, e.g.*, 42 U.S.C. § 300a-7(c) (prohibiting recipients of certain federal funds from discriminating on certain bases). But the Statutes do not define the key terms listed in the Rule's definitions section. And even when definitions are provided, they are explicitly non-exhaustive. *See, e.g.*, 42 U.S.C. § 238n(c) (defining "health care entity" as including a non-exhaustive list). Furthermore, the Statutes do not explicitly detail how HHS is to ensure that recipients comply with the Statutes' conditions. And as previously discussed, the Statutes do not create private rights of action. *See* Defs.' Mem. 28. Surely Congress did not intend to impose such significant conditions on federal funds without also authorizing HHS to employ longstanding procedures to enforce those conditions with respect to the funds that HHS disburses and administers and, to the extent a term is ambiguous, to clarify such ambiguity. These are quintessentially interstitial questions; they are important for the administration of the Statutes, but the Statutes themselves do not answer them.

In addition, the administration of federal awards connected to the Federal Conscience Statutes is complex. "The HHS Office of the Secretary and its 11 Operating Divisions (OpDivs) administer more than 300 programs covering a wide spectrum of activities." HHS, FY 2018 *Agency Financial Report* 7 (Nov. 14, 2018), <https://www.hhs.gov/sites/default/files/fy-2018-hhs-agency-financial-report.pdf>. In total, "HHS is responsible for more than a quarter of all federal outlays and administers more grant dollars than all other federal agencies combined." *Id.* And the Rule, which addresses a variety of statutes that apply in different contexts, is estimated to cover 502,899 entities. *See* 84 Fed. Reg. at 23,235.

Last, HHS has significant expertise developed over years of enforcing civil rights laws in

the health care context, including the Federal Conscience Statutes. HHS has promulgated regulations regarding the Federal Conscience Statutes since 2008. OCR has also investigated complaints of discrimination, issued notices of violations, and negotiated settlements with entities found to have violated the Federal Conscience Statutes and implementing regulations. Its staff has experience overseeing and ensuring the protection of civil rights, including protection from discrimination, such as religious discrimination. Based on this experience, HHS determined there was a need to provide more concrete and detailed guidance on how the agency intends to enforce conscience protections with respect to recipients of its federal funds.

Plaintiffs offer two additional, unmeritorious arguments against *Chevron* deference. First, they argue that *Chevron* deference is unavailable to an agency when other agencies also administer the same statute. *See* PP Opp'n 12. However, the Supreme Court has never cabined agency deference to statutes that delegate authority to a single agency. In fact, the statute at issue in *Chevron*, the Clean Air Act, delegates authority to the Environmental Protection Agency (EPA) *and* states. *See* 42 U.S.C. § 7402. The Supreme Court nevertheless afforded deference to the EPA's interpretation of that statute. *Chevron*, 467 U.S. at 866. The lone, out-of-circuit decision that Plaintiffs cite, *DLS Precision Fab LLC v. U.S. Immigration & Customs Enforcement*, 67 F.3d 1079 (9th Cir. 2017), does not support Plaintiffs' position. That court simply observed in a footnote that it would not defer to an Office of the Chief Administrative Hearing Officer (OCAHO) opinion that interpreted a statute that was "generally applicable to all federal agencies." *Id.* at 1087 n.1. The court did not hold, as Plaintiffs suggest, that courts may not defer to an agency's interpretation of a statute that is administered by multiple federal agencies. Significantly, unlike the OCAHO opinion in *DLS Precision Fab LLC*, which offered a general interpretation of a statute, this Rule is expressly limited to funds that HHS administers. *See* 84 Fed. Reg. at 23,170. HHS does not

claim deference outside of this context, such as when another agency disburses funds governed by the Federal Conscience Statutes.

Plaintiffs also point to several factors that the Supreme Court considered in declining to afford deference to an interpretive rule that the Attorney General issued in *Gonzales v. Oregon*, 546 U.S. 243 (2006). *See* PP Opp'n 9–10. However, Plaintiffs' selective reading of *Gonzales* cannot mask the stark differences between the interpretive rule at issue in that case and the Rule at issue here. In *Gonzales*, the Supreme Court declined to afford *Chevron* deference to the interpretive rule for a number of reasons, including that (1) the Attorney General issued the rule “without consulting . . . anyone outside his Department,” *id.* at 253, (2) made medical judgments outside of his expertise and rulemaking authority, *id.* at 258, and (3) failed to follow certain procedures that the relevant statute required, *id.* at 260–63. Here, by contrast, HHS considered input from a wide variety of sources in promulgating the Rule, limited the Rule's applicability to health care funds that HHS alone administers in the exercise of its expertise, and followed applicable procedural requirements. Thus, to the extent any of the Federal Conscience Statutes' terms are ambiguous, HHS's interpretations are entitled to *Chevron* deference.

B. The Rule's Definitions Are Consistent With the Federal Conscience Statutes

Plaintiffs raise a number of counterarguments to each definition, which may be dismissed in turn.

1. “Assist in the Performance”

Plaintiffs raise two objections to HHS's definition of this phrase: that the Church Amendments are limited to the “actual performance” of a procedure and that the legislative history is contrary to the Rule's definition. *See* PP Opp'n 21–23. Neither objection is correct. First, Plaintiffs offer no support for the proposition that the Church Amendments are limited to actions directly connected to “the actual performance, i.e. *execution*, of an abortion or sterilization

procedure,” PP. Opp’n 22. As Defendants explained in their opening brief, the statute covers both *performance* and *assistance in the performance*. *See* Defs.’ Mem. 30–31; *see also*, e.g., 42 U.S.C. § 300a-7(d) (“No individual shall be required to *perform* or *assist in the performance* of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his *performance* or *assistance in the performance* of such part of such program or activity would be contrary to his religious beliefs or moral convictions.” (emphasis added)). Plaintiffs fail to respond to any of Defendants’ points regarding the standard dictionary definition of “assist” or how Plaintiffs’ proffered definition fails to give meaning to Congress’s decision to protect both performance *and* assistance in the performance, which necessarily covers more than the actual execution of the procedure itself. Instead, Plaintiffs conjure highly attenuated examples that have no basis in the Rule. *See* PP Opp’n 22. However, as HHS has explained, whether an action would constitute assistance in the performance of a procedure would depend on whether the action “has a specific, reasonable, and articulable connection to furthering a procedure” and “whether aid was provided by [the] action.” *See* 84 Fed. Reg. at 23,263.

Second, the legislative history that Plaintiffs identify, *see* PP Opp’n 22–23, is entirely consistent with the Rule’s definition. At the outset, Plaintiffs overstate the impetus for the Church Amendments. Although the injunction that Plaintiffs cite may have been *a* motivation for the Church Amendments, it was not the *sole* motivation. In fact, the Church Amendments, which were enacted piecemeal in the years following *Roe v. Wade*, 410 U.S. 113 (1973), were motivated by broader “debates over whether judicially recognized rights to abortions, sterilizations, or related practices might lead to the requirement that individuals or entities participate in activities to which they have religious or moral objections.” 84 Fed. Reg. at 23,171. Furthermore, although

Defendants have already explained how Senator Church’s floor statement is consistent with the Rule’s definition, Defs.’ Mem. 31–32, Plaintiffs assign undue weight to that statement. The Second Circuit has been clear on this point: Where “[t]here are no committee reports accompanying the enactment of [a statute,]” courts may “look to statements made by sponsors of the legislation on the floor of Congress for an expression of legislative intent.” *In re Ionosphere Clubs, Inc.*, 922 F.2d 984, 990 (2d Cir. 1990). But here, the House issued a report that accompanied the Church Amendments, and it did not incorporate Senator Church’s floor statement. *See* Defs.’ Mem. 32. Accordingly, Senator Church’s statement is entitled to limited weight.

2. **“Discriminate or Discrimination”**

Plaintiffs’ rhetoric regarding this definition soars far beyond the actual text of the definition. As explained in Defendants’ opening brief, the definition simply provides examples of what *might* constitute discrimination “as applicable to, and to the extent permitted by, the applicable statute,” *see* 84 Fed. Reg. at 23,263 (subsections (1) through (3)), as well as exceptions, *see id.* (subsections (4) through (6)). The definition does not state, as Plaintiffs suggest, *see* PP Opp’n 17–18, that employers must take *all* steps—even unreasonable ones—to accommodate conduct protected by the Federal Conscience Statutes. Nor does it state, as Plaintiffs suggest, that employers may only reassign an employee if the employee voluntarily accepts such reassignment. On this latter point, Plaintiffs appear to incorrectly infer a prohibition in the Rule from the first safe harbor provision: Although Plaintiffs are correct that “voluntary acceptance of an effective accommodation of protected conduct, religious beliefs, or moral convictions, will not, by itself, constitute discrimination,” 84 Fed. Reg. at 23,191, it does not follow that offering an accommodation that is not accepted means that discrimination has occurred. Subsection 4 simply identifies certain conduct that does not constitute discrimination, but whether the converse constitutes discrimination depends on “the context of each underlying statute at issue, any other

related provisions of the rule, and the facts and circumstances.” *Id.* at 23,192; *see also* PP Opp’n 19 (agreeing that discrimination “is sensitive to context and circumstance”).

Plaintiffs’ responses to Defendants’ opening brief, PP Opp’n 19–21, are similarly baseless. First, the preface to the “discriminate or discrimination” definition that it “includes [certain conduct], as applicable to, and to the extent permitted by, the applicable statute” is not circular; it reflects HHS’s intent to “ensure[] that the definition is not overly broad.” 84 Fed. Reg. at 23,190. This is also why the definition is framed as a non-exhaustive list, rather than a categorical inventory of what constitutes discrimination. Second, Plaintiffs identify no basis in the Federal Conscience Statutes for an undue hardship exception, *see* PP Opp’n 20–21; it was consistent with these Statutes for the Rule not to include such an exception. Contrary to Plaintiff’s view, *Jackson v. Birmingham Board of Education* does not hold otherwise. In that case, the Supreme Court identified specific reasons why Title IX contained an implied prohibition on retaliation, which Title VII expressly contains. *See* 544 U.S. 167, 173–77 (2005). Here, by contrast, Plaintiffs have not explained why the Federal Conscience Statutes should be read to imply an undue hardship exception where none is explicit in the Statutes. Given the absence of any indication that Congress meant to imply such an exception, it was not improper for HHS to note that the Statutes, in contrast to Title VII, do not contain an undue hardship exception.

3. “Health Care Entity”

Plaintiffs’ threadbare arguments regarding HHS’s definition of “health care entity” likewise do not pass muster. With respect to the Coats-Snowe Amendments, Plaintiffs claim—without support—that the statute focuses on “a select group of individuals.” PP Opp’n 26. But as Defendants explained in their opening brief, the statute’s definition of “health care entity” contains a non-exhaustive list of examples; the statute’s definition “includes” these examples, but is not limited to them. *See* 42 U.S.C. § 238n(c). Plaintiffs do not contest Defendants’ assertion that the

dictionary definition of “health care entity” includes “other health care professional[s], including a pharmacist; health care personnel; . . . or any other health care provider or health care facility.” 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2). Rather, they point to floor statements by the bill’s sponsors, which as discussed *supra* carry limited weight.

At any rate, the statements of Senators Coats and Snowe do not contradict HHS’s definition. Senator Coats’ apparent goal of addressing “the question of training for induced abortions,” 142 Cong. Rec. 5,158 (1996), does not preclude including pharmacists in the definition of “health care entity.” This is especially so here, where the statutory protection extends beyond training for induced abortions to any health care entity that “refuses . . . to perform such abortions, or to provide referrals for . . . such abortions, as well as refuses to make arrangements for such activities.” 42 U.S.C. § 238n(a)(1), (2). And Senator Snowe’s reference to people who are affected by the statute similarly does not imply that people she did not mention are excluded from the statute’s reach, particularly given that such a limitation is not contained in the statute’s text.

Plaintiffs’ final point that a pharmacist never participates in a program of training in the health professions, *see* PP Opp’n 28, is nonsensical. As health professionals, pharmacists can engage in such training. And to the extent that they do not, the training portion of the Coats-Snowe Amendment and the Rule does not apply to them. *See* 84 Fed. Reg. at 12,196 (“Whether a particular protection in those three laws applies to a pharmacist or pharmacy in a particular case, or whether it applies to any of the examples in these definitions, is a separate question that will be determined in the context of the factual and legal issues applicable to the situation.”).

Plaintiffs’ reading of the Weldon Amendment is similarly inconsistent with the statutory text. Once again, Plaintiffs do not respond to Defendants’ basic point that the Rule’s definition is consistent with the dictionary definition of “health care entity.” They simply state—again, without

support—that Congress created a “narrow list” and that the Rule’s definition is broader than their envisioned narrow list. *See* PP Opp’n 27. Saying a thing does not make it so. Plaintiffs offer no reason why the Weldon Amendment preclude a plan sponsor or other entities included in the Rule’s definition from its reach. *See* PP Opp’n 27–28. Plaintiffs’ only substantive response, that the appearance of certain terms in other Federal Conscience Statutes precludes their inclusion in the Weldon Amendment, *id.* at 27 n.14, ignores Defendants’ point in their opening brief that statutes enacted by different Congresses as different public laws are not subject to the sort of inter-textual comparison that Plaintiffs advocate. *See* Defs.’ Mem. 32.

4. “Referral or Refer For”

Finally, Plaintiffs argue that the Rule’s definition of “referral” or “refer for” is inconsistent with the Federal Conscience Statutes because it is contrary to medical ethics, lacks statutory support, and contradicts HHS’s position elsewhere. *See* PP Opp’n 24–25. They are wrong on all three points. First, Plaintiffs claim that it would be contrary to “principles of informed consent and medical ethics” to permit a nurse or counselor not to answer a question about the legality of abortion. *See id.* at 24. As an initial matter, the meaning of the term “referral or refer for” is a *legal* in nature and is not affected by medical ethics. In addition, far from being established ethical principles, the principles to which Plaintiffs point are a matter of debate within the medical community. *See* A.R. 538,670 (finding that “57% of physicians agreed that doctors must refer patients regardless of whether or not the doctor believes the referral itself is immoral”). And at any rate, the Rule “do[es] not prohibit any doctor or health care entity from providing information to their patients—or referring for a medical service or treatment—if they feel they have a medical, legal, ethical, or other duty to do so.” 84 Fed. Reg. at 23,200. Rather, the Rule protects certain individuals from “being coerced by entities receiving Federal funds to violate their moral or religious convictions.” *Id.*

Second, Plaintiffs point to the dearth of legislative history regarding the meaning of “referral” or “refer for.” *See* PP Opp’n 24. But this does not mean that the Rule’s definition should be set aside. First, Defendants have argued that they prevail at *Chevron* step one based on the dictionary definition of the terms, an argument that Plaintiffs do not dispute, *see id.* at 24–25. In the alternative, to the extent there is any ambiguity, this is precisely the sort of interstitial gap-filling that indicates an implied delegation of rulemaking authority. *See Walton*, 535 U.S. at 222. As such, it is of no moment that Defendants have not pointed to evidence in the statutes or legislative histories; this is not a requirement for agencies at *Chevron* step two. Rather, the Court simply asks whether the agency’s definition is “a reasonable interpretation” of the statute. *See Chevron*, 467 U.S. at 844.

Plaintiffs’ final point, that HHS purportedly has conceded to a narrower definition of “referral” or “refer for” in litigation challenging a different rule, *see* PP Opp’n 25, is meritless. The Title X brief that Plaintiffs cite contrasts “nondirective pregnancy counseling” with “referrals,” and it arose in the context of a particular appropriations rider addressing the Title X program that mentions only “nondirective pregnancy counseling.” That brief does not purport to interpret the terms “referral” or “refer for” in any statute, let alone the Coats-Snowe and Weldon Amendments that are at issue here. HHS accordingly did not take a position in that brief on whether providing certain types of counseling might constitute a “referral” or “referring for” within the meaning of those Federal Conscience Statutes. There is no conflict between HHS’s positions.

III. The Rule Is Consistent with Other Provisions of Law

A. EMTALA

Plaintiffs claim that the Rule somehow “order[s] third parties to violate” the Emergency Medical Treatment and Active Labor Act (EMTALA). *Planned Parenthood Fed’n of Am., Inc. v. Azar*, No. 1:19-cv-05433-PAE, Joint Mem. of Law in Supp. of Pls.’ Mot for Prelim. Inj. at 35,

ECF No. 20; *see also id.* at 28–34. Not so. As Defendants explained in the preamble to the Rule and in their opening brief, HHS believes the Rule can be read harmoniously with EMTALA and does not foresee any circumstance in which fulfilling the requirements of EMTALA would violate the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,183; Defs.’ Mem. 46–47. OCR, moreover, “intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law.” 84 Fed. Reg. at 23,183. Plaintiffs may continue to abide by EMTALA’s requirements without any reasonable fear that doing so would run afoul of the Federal Conscience Statutes.

Rather than accept HHS’s explicit acknowledgement that following EMTALA will not give rise to a conflict with the Federal Conscience Statutes, Plaintiffs attempt to create potential conflict where none exists. To do so, Plaintiffs again mischaracterize the definition of “discriminate” and “discrimination” in the Rule to suggest that Plaintiffs and their health departments have no way of assessing when or if a particular health care entity will object to providing any particular service. PP Opp’n 30–31. Plaintiffs claim the Rule demands emergency departments to “anticipate every possible basis for a religious or moral objection.” PP Opp’n 32 (citation omitted). Yet, the Rule is explicit that a recipient of federal funds subject to the Rule may “require a protected entity to inform it of objections to performing, referring for, participating in, or assisting in the performance of specific procedures . . . to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith” to perform or assist in the performance of that procedure. 84 Fed. Reg. at 23,263. It is simply not the case, therefore, that Plaintiffs and their health departments lack the tools to ensure that emergency care is available to all patients. HHS explicitly permits covered entities to make non-discriminatory staffing decisions and to develop other methods precisely to ensure that patients receive needed care.

Plaintiffs' real concern, it seems, is that they may need, in some circumstances—for example, if one of their employees is not willing to accept the accommodation Plaintiffs offer—to engage in some level of “double staff[ing]” in order to avoid discriminating against an objecting employee. PP Opp'n 32, 35. However, the fact that Plaintiffs may incur additional costs in some circumstances to comply with conditions on federal funds does not create a conflict with EMTALA—particularly given that EMTALA’s obligations are limited to the capabilities of the particular hospital at issue, 42 U.S.C. § 1395dd(b); Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072, 78,087 (Dec. 19, 2008).²

Finally, Plaintiffs also claim that some religiously affiliated hospitals may decide to turn away patients in some circumstances that would run afoul of EMTALA. PP Opp'n 33–34. Whether or not that is true, Plaintiffs, and their health departments, are, of course, free under the Rule to perform whatever lawful services and treat whatever patients they wish. Plaintiffs therefore lack standing to challenge the Rule on the basis of what some *other* covered entity may or may not choose to do under the Rule, when Plaintiffs themselves apparently have no intention to restrict what services they will perform. And, even if the conduct of third parties not before the Court were somehow relevant, as Plaintiffs themselves point out, EMTALA creates a private right of action

² In a footnote, Plaintiffs point to the possibility that an emergency medical technician or paramedic may object to transporting a person with an ectopic pregnancy for an abortion as a situation where EMTALA and the Federal Conscience Statutes may conflict, and Plaintiffs fault HHS for allegedly stating that it would “depend on the facts and circumstances” whether failure to perform emergency care in that circumstance would violate EMTALA. PP Opp'n 29 n.15. Plaintiffs misconstrue the portion of the preamble on which they rely. HHS’s statement was in response to comments addressing the definition of “assist in the performance,” and HHS explained that it would “depend on the facts and circumstances” whether “driving a patient to a procedure should []ever be construed to be assisting in the performance of a procedure,” not whether a covered entity could somehow be excused from EMTALA. 84 Fed. Reg. at 23,188.

for violations, *see* PP Opp'n 30 (citing 42 U.S.C. § 1395dd(d)(2)(A)), which will itself ensure that hospitals subject to EMTALA meet the statute's obligations.

B. Medicaid Informed Consent Requirements

Plaintiffs accuse Defendants of relying on "counsel's post-hoc rationalizations" to show why Medicaid's informed consent requirements are not implicated by the Rule. *See* NY Opp'n 11. But the Court need not rely on the explanation of counsel. The provision of the Medicaid statute Plaintiffs cite, 42 U.S.C. § 1396u-2(b)(3)(B), explicitly provides only a rule of construction with respect to the narrow requirement in § 1396u-2(b)(3)(A), which prohibits Medicaid managed care organizations from restricting communications between patients and covered health care professionals. *See also* 84 Fed. Reg. at 23,210 (describing § 1396u-2(b)(3)(B) as "rule[] of construction"). The language in § 1396u-2(b)(3)(B) that Plaintiffs cite regarding state disclosure requirements, moreover, consists of a limitation *only* to the rule of construction in that subparagraph. *Id.* Plaintiffs entire argument, therefore, rests on a narrow limitation within a rule of construction to a single provision of the Medicaid statute. Under the terms of the statute, unless the state disclosure requirement specifically relates to the specific communications covered by § 1396u-2(b)(3)(A)—which again, Plaintiffs do not allege—then § 1396u-2(b)(3)(B) is of no moment and does not create any potential conflict with the Rule.

C. Title X

Plaintiffs also continue to press their argument that the Rule "directly conflicts with Title X." PP Opp'n 35–36. Plaintiffs' claim fails for multiple reasons. First, Plaintiffs do not identify any portion of the Title X statute with which the Rule allegedly conflicts. And, indeed, there is nothing in Title X that could plausibly prevent HHS from implementing the Federal Conscience Statutes. *See* Pub. L. No. 91-572, 84 Stat. 1504 (1970). Title X's statutory language has not

materially changed since the 1970s. Section 1001(a) authorizes the Secretary of HHS to make grants and enter into contracts with public or private nonprofit entities,

to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).

42 U.S.C. § 300(a). Section 1006(a) states that “[g]rants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate.” *Id.* § 300a-4(a). Section 1008 requires that “[n]one of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.” *Id.* § 300a-6. Nothing in the Title X statute is inconsistent with the Federal Conscience Statutes or the Rule; and, indeed, the prohibition on federal funding of programs where abortion is a method of family planning in section 1008 complements Congress’s restrictions on funding in the Federal Conscience Statutes.³

Unable to support their argument with anything in the text of Title X, Plaintiffs rely instead on a rider in Congress’s annual HHS appropriations act that—in addition to stating that funds appropriated to Title X projects “shall not be expended for abortions”—requires that “all pregnancy counseling shall be nondirective.” *E.g.*, HHS Appropriations Act 2019, Pub. L. No. 115-245, Div. B, 132 Stat. 2981, 3070–71 (2018). Plaintiffs fail to explain how the Rule interferes with the ability of Title X projects to provide nondirective pregnancy counseling. Neither Title X nor the March 2019 Title X Rule, nor the Rule at issue here requires funding recipients to engage in pregnancy counseling *at all*, much less requires funding recipients to provide counseling on any

³ In their opening briefs, the Planned Parenthood and NFPRHA Plaintiffs suggested that the Rule may be inconsistent with the requirement in Title X that family planning services be voluntary, and that the Rule “flouts the Congressional purpose of the Title X program.” PP Opp’n 34–36. Planned Parenthood and NFPRHA appear to have abandoned those arguments in their most recent brief. *See* PP Opp’n 35–36.

particular pregnancy outcome. Plaintiffs and their health departments are free to provide nondirective pregnancy counseling as they deem appropriate, including on abortion. The fact that Plaintiffs or their health departments may, in some circumstances, need to make arrangements to prevent discrimination against an employee who objects to providing counseling on abortion does not prevent them from offering nondirective pregnancy counseling nor render any pregnancy counseling they choose to provide “directive.”

D. Section 1554 of the ACA

Plaintiffs press on with their extraordinary claim that Section 1554 of the ACA—which neither mentions any of the Federal Conscience Statutes nor otherwise provides any indication that Congress intended to limit those, in some cases, decades-old restrictions—prevents HHS from implementing any regulation that, *inter alia*, “creates [a] barrier,” “impedes [] access,” or “limits the availability of health care treatment,” including by allowing a health care entity with an objection to providing, for instance, an abortion, to abstain from doing so. *See* PP Opp’n 36–40. It is worth pausing to consider the incredible breadth of Plaintiffs’ argument: if they were correct, Section 1554 would render meaningless (if not completely abrogate) many Federal Conscience Statutes that touch on health care, because—by respecting the conscience rights of health care entities—those statutes, in Plaintiffs’ view, “impede access” to care. Plaintiffs’ reading of Section 1554 would also effectively mean that HHS could not put any restrictions on Medicare or Medicaid funding through regulations, which Congress could not plausibly have intended.

Fortunately, as Defendants explained in their opening brief, there is no plausible reason to accept Plaintiffs’ utterly draconian interpretation of Section 1554. *See* Defs.’ Mem. 42–46. In Section 1303(c)(2) of the ACA, Congress was absolutely clear that nothing in the ACA (including Section 1554) “shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of

willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.” 42 U.S.C. § 18023(c)(2). That provision is fatal to Plaintiffs’ argument that Section 1554 somehow interferes with implementation of the Federal Conscience Statutes through the Rule, and Plaintiffs conspicuously fail to even acknowledge Section 1303(c)(2) in their briefs.

Plaintiffs meekly attempt to suggest that they are not challenging the Federal Conscience Statutes themselves, insisting instead that the “Rule dramatically and impermissibly expands the scope of the refusal rights beyond those provided in the statutes.” PP Opp’n 40. But nowhere in Plaintiffs’ briefs do they explain why *any* regulations that give effect to the Federal Conscience Statutes, including the 2011 regulations, would not also violate Section 1554 under their theory of what that provision requires. Plaintiffs claim that the conflict stems from HHS’s “extreme interpretations” of those statutes, *id.*, but they provide no limiting principle that would allow Section 1554 to exist alongside the Federal Conscience Statutes. Indeed, as Plaintiffs interpret Section 1554, *any* condition on federal funding, or any other action of the Secretary, that has any arguable detrimental impact on the availability or quality of patient care is absolutely foreclosed by the ACA. That cannot be the law.

E. Paperwork Reduction Act

Plaintiffs continue to argue that the Rule conflicts with other provisions of law because the Office of Management and Budget (OMB) has not yet approved the assurance language required by Section 88.4(a) of the Rule, which Plaintiffs claim violates the Paperwork Reduction Act (PRA). *See* NY Opp’n 12. Plaintiffs misunderstand the PRA and what approvals are required.

The provision of the PRA on which Plaintiffs rely states that an “agency shall not conduct or sponsor the collection of information unless in advance of the adoption or revision of the collection of information . . . the Director [of OMB] has approved the proposed collection of

information or approval has been inferred, under the provisions of this section.” 44 U.S.C. § 3507. Nothing on the face of the statute required HHS to obtain OMB approval before issuing the Rule on May 21, 2019; nor do Plaintiffs point to any authority for that proposition, *see* NY Opp’n 12.

As Defendants have explained, HHS fully expects that OMB will approve the assurance requirement prior to the Rule’s revised effective date of November 22, 2019. *See* Defs.’ Mem. 51. This Court should reject Plaintiffs’ extraordinary request to strike down the Rule in its entirety because HHS has not yet obtained approval of the assurance requirement, even though that requirement has not yet gone into effect. If, hypothetically, HHS did not obtain approval before the effective date, Plaintiffs could challenge the requirements in Section 88.4(a), and only those requirements, on that basis. And they could only do so if the agency imposed a penalty for failure to comply with an unapproved collection of information. *See* 44 U.S.C. § 3512(b); 5 C.F.R. § 1320.6(b), (d). But no OMB approval is currently required because no information is currently being collected pursuant to Section 88.4(a).

Plaintiffs also suggest that HHS’s approval request submitted to OMB is somehow deficient because it did not seek OMB approval of the certification of compliance required by Section 88.4(b) *See* NY Opp’n 12. Plaintiffs, however, selectively cite HHS’s approval request to create the misimpression of a deficiency. As HHS explained in that request, it did not seek OMB approval of the specific language in the certification because OMB had already approved the language HHS will be using to operationalize the certification. *See* Information Collection Request, *Request for OMB Review and Approval*, at 5 (June 19, 2019), <https://www.reginfo.gov/public/do/DownloadDocument?objectID=92774800>.

Because HHS will have the necessary OMB approval by the time those approvals are required by the PRA, there is no basis to strike down the Rule for failure to comply with the PRA. But even if Plaintiffs were correct, and HHS were to impose a penalty for an entity’s failure to

comply with an unapproved collection of information, the PRA provides that entity with an affirmative defense. *See* 44 U.S.C. § 3512(b); 5 C.F.R. § 1320.6(b). There is no reason why HHS’s alleged failure (if there was one) to obtain OMB approval would require vacatur of the Rule.

IV. The Rule is the Product of Reasoned Decisionmaking.

As Defendants explained in their opening brief, the Rule is neither arbitrary nor capricious under 5 U.S.C. § 706(1) because HHS provided “a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n, of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted); *see also* Defs.’ Mem. 51–60. The New York Plaintiffs’ arguments to the contrary are meritless. HHS supported each challenged aspect of the Rule with sound and detailed reasoning, and Plaintiffs’ attempt to couch its policy disagreements as an APA challenge must fail. *Pub. Citizen, Inc. v. Nat’l Highway Traffic Safety Admin.*, 374 F.3d 1251, 1263 (D.C. Cir. 2004) (rejecting an “arbitrary-and-capricious challenge [that] boils down to a policy disagreement”).

A. HHS Adequately Explained Its Reasons for the Rule.

First, HHS offered a reasoned explanation for changing course from the 2011 Rule. The New York Plaintiffs claim that “[t]he Department’s reliance on the same evidence more than eight years later to reach precisely the opposite conclusions—with no explanation of why” the agency’s 2011 conclusions were incorrect—is arbitrary and capricious.” NY Opp’n 21 (citing *Organized Vill. of Kake v. U.S. Dept. of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc)). But the Secretary is “entitled . . . to give more weight” to certain concerns that were raised in previous rulemakings, “even on precisely the same record.” *Organized Vill. of Kake*, 795 F.3d at 968. Here, the agency proposed a new rule because “[a]fter reviewing the previous rulemakings, comments from the public, and OCR’s enforcement activities,” it concluded that the 2011 Rule “created confusion over what is and is not required under Federal health care conscience laws and narrowed OCR’s

enforcement authority.” 83 Fed. Reg. at 3,887. Moreover, in promulgating the Rule challenged here, the agency did not merely rely on the same record used in the past. In addition to a survey conducted in 2009 and comments received in the 2008 and 2011 rulemakings, the agency factored in (1) recent, documented instances of alleged and demonstrated conscience discrimination, such as litigation regarding new, potentially discriminatory laws passed by various States, (2) complaints that OCR has received in recent years, and (3) comments received during the 2018–19 rulemaking.⁴ *See* 84 Fed. Reg. 23175–79; *see also* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,887–891 (2018).

Plaintiffs separately assail HHS’s reliance on recent complaints that OCR received to argue that the agency failed to acknowledge record evidence directly contradicting its assertions. NY Opp’n 13–20. But again, HHS considered the complaints received in conjunction with all of the factors discussed above and merely noted that the complaints *alleged* violations of the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,245. The presence or absence of complaints does not,

⁴ *See, e.g.*, Administrative Record (AR) 135,736–746, Ex. 4 (comment from a “diverse group of faith-based ministries” stating that “[f]or the wellbeing of patients and the integrity of the [health care] profession, . . . healthcare professionals must be free to practice medicine in accordance with their professional judgment and ethical beliefs” and noting “examples of violations against conscience rights in healthcare, indicating that the threat to conscience rights is rising”); AR 134,132–136, Ex. 3 (comment from Ascension, a faith-based healthcare organization, applauding HHS “for taking steps to protect the religious freedoms of all Americans, especially when it comes to healthcare workers and organizations that are called by their faith to serve *all* persons, especially those who are poor and vulnerable”); AR 139,527–529, Ex. 5 (comment from Catholic Health Association noting that “[t]he lack of implementing regulations and of clarity concerning enforcement mechanisms for [the Federal Conscience Statues] has stymied their effectiveness”); AR 133,746–758, Ex. 2 (comment from Alliance Defense Fund supporting the proposed Rule because it seeks “to not only raise awareness of conscience rights but to put . . . teeth into federal protections for those rights”); AR 28,049–053, Ex. 1 (comment from various religious organizations stating that the proposed Rule would “help guarantee that health care institutions and professionals are not pushed into [a] Hobson’s choice”).

by itself, paint a full picture of whether individuals and entities understand their rights and obligations under the Federal Conscience Statutes; as HHS indicated elsewhere, the agency is concerned that “segments of the public have been dissuaded from complaining about religious discrimination in the health care setting to OCR as the result, at least in part, of [the agency’s previous,] unduly narrow interpretations of the Weldon Amendment.” 84 Fed. Reg. at 23,179.

And while Defendants already acknowledged that many of the complaints that OCR received related to matters that are outside the scope of the Federal Conscience Statutes, a sizeable number of complaints *did* implicate the relevant Statutes and underscore a need to both clarify the scope of, and more robustly safeguard, the conscience rights protected by the Statutes.⁵ While the complaints in the record are not the sole reason for the Secretary’s decision to promulgate the Rule, they represent one factor the Secretary considered in determining that “there is a significant need

⁵ Defendants cited some of those complaints in their opening brief as examples, *see* Defs.’ Mem. 53, and include others here, *see, e.g.*, AR 542,017–26, Ex. 6 (complaint that California’s health insurance abortion coverage mandate violates the Weldon Amendment); AR 542,151, Ex. 7 (nursing student alleges discrimination due to request for an exemption from assisting in abortions); AR 542,229–60, Ex. 13 (complaint against Illinois statute mandating healthcare providers exercising conscience rights to engage in compelled speech and referrals); AR 542,285, Ex. 8 (complaint against State of Hawaii’s statutory mandate that religious-based alternative pregnancy centers must advertise for state-funded abortions); AR 542,316–24, Ex. 9 (complaint against Pennsylvania’s involvement in contraception mandate litigation); AR 545,932, Ex. 12 (nurse alleges that university hospital refused to hire her for full-time faculty position because of her views regarding abortion); AR 542,337, Ex. 10 (pediatric nurse complains that hospital informed her that she could no longer work in the health department clinics if she was unwilling to participate in the provision of abortion-related services) AR 544,612–23, Ex. 11 (complaint against the University of Vermont Medical Center for deceptively coercing nurse to participate in elective abortion); AR 544,945–52, Ex. 14 (complaint by pharmacist who objects to filling birth control prescriptions).

to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of” the Federal Conscience Statutes. 84 Fed. Reg. at 23,175.⁶

B. HHS Reasonably Formulated the Rule’s Definitions.

The New York Plaintiffs next claim that HHS’s modifications of its proposed definitions in response to the comments received “utterly failed to address the concerns raised.” NY Opp’n 25. The record flatly contradicts this claim.

The agency responded to the major categories of comments regarding each challenged definition, and explained why it agreed or disagreed with each set of comments. 84 Fed. Reg. at 23,186–204. Defendants have already explained that, in response to comments raising various policy concerns and requesting that the definition of “assist in the performance” be taken out of the Rule, narrowed, or clarified, the agency provided detailed reasoning or made changes to the definition in the final rule, Defs.’ Mem. 55; *see also* 84 Fed. Reg. at 23,186–89. HHS responded in similarly robust terms to comments submitted regarding the other challenged definitions. *See* 84 Fed. Reg. at 23,189–93 (responding to comments about the proposed definition of “discriminate” or “discrimination” by explaining why the commenters’ concerns did not fall within

⁶ The New York Plaintiffs claim that two of the three complaints that Defendants highlighted in their opening brief could not “plausibly form a basis for concluding that [HHS] needed greater enforcement authority.” NY Opp’n 18. But the complaints indicate both general and specific concerns about the conscience rights of individuals in the health care field: the 2018 letter from the American Association of Pro-Life Obstetricians and Gynecologists highlights the “continuing chilling effects on [the] conscientious performance of ob-gyn services” by pro-life obstetricians, Defs.’ Mem. Ex. 1 at 11, ECF No. 147-1. And the 2018 complaint by a Washington State Department of Corrections employee alleging discrimination based on the employee’s objection to providing hormone therapy to incarcerated transgendered persons could relate to the Federal Conscience Statutes that protect conscience objections to sterilization or the Church Amendments that more broadly protect conscience rights, if applicable. *See id.* at 44. These complaints, and others, support HHS’s conclusion that the public needs more information about what is and is not protected under the Federal Conscience Statutes and that OCR needs more tools to better ensure compliance with the Statutes’ conditions on HHS’s funding.

the scope of the applicable Federal Conscience Statutes or by modifying the definition, for example, by clarifying that “employers may require a protected employee to inform them” of protected conscience objections “to the extent there is a reasonable likelihood that the protected entity or individual may be asked in good faith” to undertake an objected-to activity, “and that the employer may use alternate staff or methods to provide or further any objected-to conduct, subject to certain limitations designed to protect the objecting person.”); 84 Fed. Reg. at 23,194–97 (explaining why the agency disagreed with comments to either broaden or narrow the proposed definition of “health care entity,” answering questions about HHS’s statutory authority to craft the definition under the Weldon and Coats-Snowe Amendments, and accepting a recommendation to include pharmacies and pharmacists in the definition); 84 Fed. Reg. at 23,199–202 (agreeing with comments that the proposed definition of “referral or refer for” is appropriate, explaining why HHS disagreed with comments stating that the definition exceeds the scope of the Weldon and Coats-Snowe Amendments, discussing the definition’s impact on California’s Reproductive FACT Act and the federal DeConcini Amendment, and narrowing the definition to apply to an objected-to activity that is a “reasonably foreseeable outcome” of the referral, rather than merely a “possible outcome” in response to commenters’ concerns over the definition’s potential scope).

Plaintiffs argue that HHS failed to respond to two sets of comments regarding the definition of “discriminate” or “discrimination.” *See* NY Opp’n 26–27 (claiming that the agency “nowhere” addressed concerns about employees providing advance notice of a conscience objection or the “double bind” of its definitions upon health providers). However, HHS *did* modify the definition of “discriminate” or “discrimination” “to clarify that . . . employers may require a protected employee to inform them of objections to referring for, participating, or assisting in the performance of” specific activities “to the extent there is a reasonable likelihood that the protected

entity or individual may be asked in good faith to refer for, participate in, or assist in the performance of such conduct, and that the employer may use alternate staff or methods to provide or further any objected-to conduct, subject to certain limitations designed to protect the objecting person.” 84 Fed. Reg. at 23,191. This modification would appear to assuage Plaintiffs’ concerns about being able to receive advance notice of protected employees’ conscience objections. To the extent Plaintiffs complain that the Rule does not categorically require all protected employees to provide advance notice of any conscience objections in all situations, they fail to identify any applicable law that requires a protected employee to voice all objections in advance (including situations in which the employee does not know in advance that she will be asked to perform a particular function). Indeed, none of the Federal Conscience Statutes contain any such advance notice requirements and, thus, the agency is not required to include them. *See, e.g.*, 42 U.S.C. § 300a-7 (Church Amendments); 42 U.S.C. § 238n(a) (Coats-Snowe Amendment); Pub. L. No. 115-245, 132 Stat. 2981, 3118 (most recent iteration of the Weldon Amendment); 42 U.S.C. §§ 18081, 18023(b)(1)(A). (b)(4), 18113, 14406(1) (certain conscience protection provisions in the Patient Protection and Affordable Care Act).

As for the “double bind” comments that Plaintiffs reference, the commenters in question stated concerns about the Rule’s impact on “emergency departments, ambulance corps . . . and other urgent care settings.” AR 140,486; *see also* NY Opp’n 24. But HHS explained that it “generally agrees . . . that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and antidiscrimination laws,” 84 Fed. Reg. at 23,183. Moreover, the agency made clear that the emergency transportation of individuals who may hypothetically seek an objected-to service or procedure or the “emergency transportation of persons experiencing unforeseen complications

after, for example, an abortion procedure,” would not generally implicate the definition of ‘assist in the performance of’ an abortion, because “the complications in need of treatment would be . . . unforeseen and unintended.” 84 Fed. Reg. at 23,187.⁷

HHS therefore adequately responded to comments and reasonably supported the definitions in the Final Rule. Plaintiffs may “disagree with [the agency’s] policy balance, but it does not reflect a failure to consider relevant factors.” *Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 210–11 (D.C. Cir. 2007).

⁷ The New York Plaintiffs mention two additional sets of comments and apparently suggest that HHS did not consider them, either. *See* NY Opp’n 25 (discussing comments (1) concerning burdens of a purportedly expanded “universe of potential objectors beyond clinicians to other workers” and (2) evincing confusion about how the Rule’s definitions would impact collective bargaining agreements).

As to the first set of comments, HHS considered their substance in at least three places. 84 Fed. Reg. 23,186–87 (responding to comments that the proposed definition of “assist in the performance” was too broad because it potentially permitted objections by persons “preparing a room for an abortion or scheduling an abortion,” by (1) noting that “the proffered examples are properly considered as within the scope” of the Federal Consciences Statutes since such activities “are necessary parts of the process of providing an abortion,” and (2) tightening the definition to “preclude vague or attenuated allegations” of assisting in a procedure or health service program, etc.); *id.* 23,187–88 (acknowledging comments that the proposed definition was too broad because it “extends beyond health care professionals and includes other members of the workforce,” and deleting the reference to workforce members); *id.* 23,288–363 (examining the Rule’s impact on physicians, hospitals, and other health care institutions, and concluding that despite some added burdens on affected entities, the Rule “creates net benefits” and “is tailored to impose the least burden on society”).

As to the second set of comments, New York fails to explain why two cursory references to the Rule’s potential impact on labor agreements, which were not submitted by any plaintiff and which failed to contain any meaningful analysis or data for the agency to evaluate, crosses the “threshold requirement of materiality before any lack of agency response or consideration becomes of concern.” *Portland Cement Ass’n v. Ruckelshaus*, 486 F.2d 375, 394 (D.C. Cir. 1973) (superseded by statute on other grounds); *see also Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 553–54 (1978); *accord Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984). Besides, it appears self-evident that a provision in a labor agreement that conflicts with federal law should not be enforced.

C. HHS Considered All Important Aspects of the Problem.

Finally, the New York Plaintiffs complain that HHS failed to consider the Rule’s purported impact on a host of matters such as the public health, other statutory frameworks, and “basic medical ethics.” NY Opp’n 26–38. These arguments all fail.

Public Health and Specific Patient Populations. First, Plaintiffs continue to claim that the agency failed to consider the Rule’s impact on “reducing access to care for large numbers of people . . . who already face barriers to access.” NY Opp’n 26. But as Defendants already explained in their opening brief, HHS *did* consider this issue and reasonably concluded that the Rule would not harm access to care, in part because implementation and enforcement of the Federal Conscience Statutes “would help alleviate the country’s shortage of health care providers,” 84 Fed. Reg. at 23,180, as the statutes make it easier for health care professionals to perform their jobs while staying true to their religious or moral beliefs, and in part because the agency was unaware of any data or persuasive reasoning, presented by commenter or otherwise, demonstrating that the Rule could negatively impact access to care. *See id.* at 23,180–82. As noted in the Rule, “[a]ccess to care is a critical concern” of HHS, 84 Fed. Reg. at 23,180, and HHS examined the commenters’ concerns closely. The agency probed commenters’ illogical assumption that “there are health care providers in underserved communities who are protected by these laws but are offering services to which they object anyway, *id.* at 23,181, and explained why it believed that the Rule would improve access to care by (1) encouraging individuals who had previously “anticipated they would be pressured to violate their consciences” to enter the health care field, *id.*; (2) preventing some health care entities from leaving the field in light of data indicating that some entities currently felt pressure to do so, *id.*; and (3) allowing an increase in the provision of health care by religious institutions, *id.* Plaintiffs’ policy disagreement over the agency’s conclusion does not warrant invalidation of the Rule. *See Owner-Operator Indep. Drivers Ass’n*, 494 F.3d at 210–11.

Nor was it arbitrary or capricious for HHS to reach this conclusion in the absence of empirical data (one way or the other) on the Rule’s potential impact on access to care. “[P]redictive calculations are a murky science in the best of circumstances, and the [agency] naturally has no access to infallible data.” *Cablevision Sys. Corp. v. F.C.C.*, 597 F.3d 1306, 1314 (D.C. Cir. 2010). Here, HHS considered studies that “specifically found that there is insufficient evidence to conclude that conscience protections have negative effects on access to care,” and Plaintiffs offer no contrary studies, in the record or elsewhere. 84 Fed. Reg. 23,810. New York does not explain why the agency would be required to perform an unworkable study in these circumstances on the specific effects of the Rule before it went into effect. *See BellSouth Corp. v. FCC*, 162 F.3d 1215, 1221 (D.C. Cir. 1999).

Title VII. Plaintiffs also claim that HHS “failed adequately to explain its departure from Title VII’s framework.” NY Opp’n 34–36. Plaintiffs’ complaint, however, is nothing more than a policy disagreement with the path HHS took in promulgating the Rule. As is evident from the preamble to the Rule, HHS clearly explained why it did not adopt the Title VII framework to implement the Federal Conscience Statutes. *See* 84 Fed. Reg. at 23,190–91. For one, Title VII contains distinct protections from the Federal Conscience Statutes, and therefore HHS was not required to incorporate the same standards from that separate statute. HHS explained that Congress’s decision to

take a different approach in Title VII as compared to [the Federal Conscience Statutes] is consistent with the fact that Title VII’s comprehensive regulation of American employers applies in far more contexts, and is more vast, variable, and potentially burdensome (and, therefore, warranting of greater exceptions) than the more targeted conscience statutes that are the subject of this rule, which are health care specific, and often procedure specific, and which are specific to the exercise of Congress’s Spending Clause authority.

Id. at 23,191. HHS did, however, consider the reasonable-accommodation standard set forth under Title VII and adopted components of that standard when modifying the definition of

“discrimination” in response to comments on the proposed Rule. *See id.* Thus, it can hardly be said that HHS failed to adequately consider or explain its choices vis-a-vis Title VII. Plaintiffs would simply prefer that HHS had made a different choice.

Costs and Benefits. Plaintiffs next charge HHS with conducting a cost-benefit analysis “so flawed that it cannot be viewed as anything other than an effort to put a thumb on the scale.” NY Opp’n 36 (citation omitted). New York’s sweeping rhetoric attempts to obscure the only specific concern it articulates with respect to the agency’s painstaking analysis: that the agency purportedly “underestimate[ed] the number of covered persons and entities” subject to the Rule. NY Opp’n 37. But as the agency explained, “[t]here is substantial overlap between persons and entities current[ly] obligated to comply with 45 CFR part 88, as based on the 2011 Rule, and persons and entities subject to at least one of the additional Federal laws that this final rule enforces.” 84 Fed. Reg. 23,231. “This overlap occurs because such persons and entities largely were, and continue to be, subject to 45 CFR part 88 by virtue of the Church Amendments, but also the Weldon Amendment and the Coats- Snowe Amendment.” *Id.* The agency used a rigorous methodology to arrive at an estimate of the number of affected individuals and entities and concluded that the Rule would newly cover approximately 65 to 130 entities to whom HHS awarded funds appropriated to the U.S. Department of State and the United States Agency for International Development, *id.* 23,235, but which HHS administers, *see id.* at 23,210–11; *see also* 83 Fed. Reg. 3,906 (estimating the persons and entities that would be newly covered by 45 C.F.R. part 88). Plaintiffs claim that “the Final Rule’s definition of ‘health care entity’ both expands *and was intended to expand* the number of regulated persons and entities considerably,” NY Opp’n 37, but that is incorrect. The Rule’s definition of “health care entity” does no more than “conform the definition to the varying texts of

the specific Federal conscience and antidiscrimination laws that use the term.” 84 Fed. Reg. at 23,195.

Medical Ethics. Finally, Plaintiffs’ assertion that the Rule is unlawful because its definitions “violate[] principles of medical ethics,” NY Opp’n 32, is unsupported by law or logic. The Rule, and the Federal Conscience Statutes that undergird them, do not require any medical professional to act unethically. Plaintiffs highlight comments raising the following concerns: (1) while “[c]urrent codes and professional standards allow individuals to refuse to provide services to which they object . . . such objections are not unlimited,” (2) “[p]hysicians have a duty to provide medically indicated care in an emergency,” and (3) physicians and other health care professionals have a duty to inform patients about all relevant options for treatment.” NY Opp’n 31. But Plaintiffs fail to articulate how the Rule unlawfully fails to account for these concerns.

First, the Rule does not force any individual to refuse to provide medical care in any given circumstance and thus does not run afoul of the medical industries’ suggested limitations on an individual’s right to object to performing certain services and procedures. *See* NY Opp’n 31. While Plaintiffs may prefer that HHS codify all internal standards developed within the medical industry, “this final rule provides for the enforcement of protections established by the people’s representatives in Congress; the Department has no authority to override Congress’s balancing of the protections.” 84 Fed. Reg. at 23,182. Second, as for physicians’ duties to provide medically indicated care in an emergency, the Rule does not infringe on that duty and, indeed, recognizes that emergency treatment and stabilization of patients “who present in an emergency does not conflict with Federal conscience and antidiscrimination laws,” 84 Fed. Reg. at 23,283. Plaintiffs do not identify a situation in which the Rule compels a physician to violate his or her ethical duties to provide medically required care in an emergency situation, and even if they could identify such

a far-fetched scenario, the Rule should not be found facially invalid on that basis. *See Ass'n of Proprietary Colls. v. Duncan*, 107 F. Supp. 3d 332, 367–68 (S.D.N.Y. 2015). Third, HHS explained that it “disagrees that the rule would violate principles of informed consent” because it “does not believe that enforcement of conscience protections, many of which have been in place for nearly fifty years, violates or undermines the principles of informed consent. The Rule will not change the obligation that, absent exigent circumstances, doctors secure informed consent from patients before engaging in a medical procedure.” 84 Fed. Reg. at 23,189.

V. Plaintiffs’ Spending Clause and Establishment Clause Claims Are Not Ripe

Plaintiffs’ remaining constitutional claims—concerning the Spending Clause and Establishment Clause—are not ripe. The ripeness analysis turns on whether the Court would benefit from awaiting a concrete enforcement action applying the Rule before assessing the merits of Plaintiffs’ constitutional claims and whether there would be any harm to Plaintiffs in the interim. For the Spending Clause, this analysis turns on when a concrete enforcement proceeding would arise that would potentially cause Plaintiffs to lose funding. For the Establishment Clause, ripeness turns on whether whether the agency’s definition of “discrimination” would affect hiring and staffing. There is no basis for the Court to adjudicate Plaintiffs’ premature claims in either instance.

In support of their Spending Clause claims, the New York Plaintiffs continue to resort to impassioned statements that they face “immediate” potential harm from loss of their federal funds. But Plaintiffs cannot dispute that they have not been the subject of any enforcement action, or that multiple steps would have to occur before any such loss of federal funds could come to pass. And of course if Plaintiffs did violate the Rule, and the agency’s informal resolution attempts failed, and the agency took enforcement action against Plaintiffs, and all other applicable procedures were exhausted, Plaintiffs offer no reason why they could not seek judicial relief *then*. It is certainly unfounded for Plaintiffs to state that they would lose money “on the day [the Rule] takes effect.”

NY Opp'n 5. And the stark differences between Plaintiffs' hyperbolic concerns about losing billions of dollars in funding and the Rule's provision for informal enforcement proceedings and other review procedures demonstrate the value of withholding judicial review until a concrete factual circumstance arises. Plaintiffs' citation to dicta from *Lujan*'s discussion of the propriety of "programmatic" challenges to agency action under the APA, which does not substantively address the ripeness factors, is not persuasive. NY Opp'n 4 (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990)).

Similar ripeness considerations about the lack of specific enforcement action have led at least two courts to decline to decide challenges to the underlying Federal Conscience Statutes on grounds that are equally applicable here. *See NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006); *California v. United States*, No. C 05-00328 JSW, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008). Plaintiffs' attempt to distinguish these cases in a footnote falls flat. Plaintiffs dismiss *NFPHRA* because it is about "constitutional standing," NY Opp'n 5 n.1, but "[s]tanding and ripeness are closely related doctrines that overlap 'most notably in the shared requirement that the plaintiff's injury be imminent rather than conjectural or hypothetical.'" *New York Civil Liberties Union v. Grandea*, 528 F.3d 122, 130 (2d Cir. 2008) (quoting *Brooklyn Legal Servs. Corp. v. Legal Servs. Corp.*, 462 F.3d 219, 225 (2d Cir. 2006)); *see also Bronx Household of Faith v. Bd. of Educ.*, 492 F.3d 89, 111 (2d Cir. 2007) (Leval, J., concurring) (noting the overlap in ripeness and standing doctrines and focusing discussion "on those decisions which concern the ripeness of the dispute, regardless of whether they speak in terms of 'ripeness' or of 'standing'"). And Plaintiffs' attempt to analogize to language in *California* regarding the possible implications of the agency's refusal to answer a specific question about the law's applicability in a particular

circumstance fails, as Plaintiffs have not identified any specific question HHS has refused to answer (as opposed to Plaintiffs' general belief that the Rule is unclear).

Plaintiffs reiterate their assertion that "billions of dollars," NY Opp'n 5, could hypothetically be affected by the Rule. But Plaintiffs have known about the potential volume of money affected by, for example, the Weldon Amendment since they first began accepting applicable funds. The key question is the immediacy of any risk to those funds. The New York Plaintiffs concede, as they must, that no action has yet been taken against them. They offer no reason why, if such an enormous (and unprecedented) penalty were imposed, they could not seek judicial relief at that time, when the Court would have a defined factual circumstance in which to judge the legality of the Rule. Resolving Plaintiffs' Spending Clause claim now would only entangle the Court in an abstract disagreement that may never arise. Plaintiffs similarly draw no support from *City of New York v. U.S. Dep't of Commerce*, 739 F. Supp. 761, 765 (E.D.N.Y. 1990), NY Opp'n 5, which states that ripeness involves "inquiry into whether the issue is purely a legal one, or whether a court could better resolve the issue in a more concrete setting, i.e., the context of a specific attempt to apply the agency decision." *City of New York*, 739 F. Supp. at 765. Here, of course, a more concrete setting would be highly helpful in cutting through Plaintiffs' untethered hypotheticals about the scope and context of enforcement action.

Turning to the Establishment Clause, Plaintiffs now appear to limit their claim to only whether the Rule's definition of "discrimination" violates the Establishment Clause. NY Opp'n 6; PP Opp'n 19, 44. But again, this claim too would benefit from further factual development. Plaintiffs do not assert that the definition of "discrimination" would violate the Establishment Clause in all of its applications. For example, the Planned Parenthood and NFPHRA Plaintiffs would presumably agree with the agency that firing an employee for exercising his or her

conscience rights protected by the Federal Conscience Statutes would be “discrimination.” Plaintiffs’ claim instead rests on the theory that the definition of “discrimination” violates the Establishment Clause in particular applications, like the prohibition against asking job applicants about their conscience objections during the hiring process. PP Opp’n 45. In assessing this claim, the Court would undoubtedly benefit from having a concrete application of the Rule in front of it.

Further, this case is far different than the case Plaintiffs cite, *Sharkey v. Quarantillo*, 541 F. 3d 75 (2d Cir. 2008), NY Opp’n 6; PP Opp’n 47, in which a dispute over the plaintiff’s entitlement to legal status was found ripe when plaintiff alleged that one official had granted her status but another had crossed it out on her paperwork. Here, enforcement would have to occur before the case reached a similarly developed stage. Plaintiffs’ citation of the lower ripeness standard in *National Organization for Marriage, Inc. v. Walsh*, 714 F.3d 682, 689 (2d Cir. 2013), NY Opp’n 6; PP Opp’n 48 n.35, is also inapposite. That case dealt with allegations that the plaintiffs’ ability to speak had been chilled. While courts have referred to the possibility that religious exercise might be “chilled” by excessive state interference in religious matters, *see, e.g.*, *Ehrens v. Lutheran Church-Missouri Synod*, 269 F. Supp. 2d 328, 333 (S.D.N.Y. 2003), *aff’d sub nom. Ehrens v. Lutheran Church*, 385 F.3d 232 (2d Cir. 2004), Plaintiffs cite no authority for the reverse proposition that a right to not have the government violate the Establishment Clause could be “chilled.”

VI. The Rule Does Not Violate the Spending Clause.

In their Spending Clause arguments, NY Opp’n 39–47, the New York Plaintiffs re-affirm that they do not object to the Federal Conscience Statutes, and double-down on their insistence that the Rule is an unconstitutional departure from the Statutes. But Plaintiffs’ assertion that there is a purportedly unconstitutional difference between the two falls flat.

The Rule, like the Federal Conscience Statutes, is unambiguous, and Plaintiffs had ample notice of the conditions attached to federal funds. As Defendants have previously explained, Defs.’ Mem. 62–63, the standard for conditions on federal funds is not perfect clarity or perfect notice. When a condition is present but “largely indeterminate,” the Spending Clause is satisfied if a state nonetheless chooses to accept the federal funds. *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002); *see also id.* (“Congress is not required to list every factual instance in which a state will fail to comply with a condition.”). Plaintiffs do not substantively dispute this contention. And Plaintiffs also acknowledge that the existence of the anti-discrimination requirements was clear to them from the Federal Conscience Statutes, *see* NY Opp’n 39, and so those requirements are thus not retroactive. Indeed, it is ironic that Plaintiffs object to the lack of clarity and specificity in the Rule, when the Rule provides additional clarity for funding recipients.

Instead, Plaintiffs argue that the Rule is insufficiently clear, calling the Rule “nonsensical” and arguing that it “contort[s]” the Statute’s requirements, conflicts with other laws, and is ambiguous. NY Opp’n 40–42. But these arguments merely restate Plaintiffs’ APA objections to the Rule, and fail for the same reasons. Confusingly, Plaintiffs also suggest that the Rule “patch[es] together” the Federal Conscience Statutes. NY Opp’n 40. Although the Rule addresses the requirements of the various Statutes and provides definitions as appropriate for each one, it does not, for example, apply restrictions that one Federal Conscience Statute places on one funding stream to additional funding streams. *Contra* NY Opp’n 41 (“[U]nlike the underlying statutes . . . Plaintiffs stand to lose all HHS funds for any perceived misstep under the Final Rule”). This is inherent in the nature of the Rule, which is a clarifying regulation that does not alter the Statute’s substantive requirements. 84 Fed. Reg. at 23,256.

In addition, the Rule, like the Federal Conscience Statutes, is not coercive. The New York Plaintiffs stray far afield in their argument that the Rule—which affects precisely the same amounts and sources of funding as the Federal Conscience Statutes—is coercive. NY Opp’n 42–44. Plaintiffs face an uphill climb with this challenge, because in the ordinary course the states are expected to simply decline federal funds if they do not wish, or no longer wish, to comply with the associated conditions. *Cf. Nat’l Fed’n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 579 (2012).

First, unlike in *NFIB*, Plaintiffs here are not faced with a binary choice to either accept a new program or sacrifice all of their funding under an existing program. As Defendants explained in their opening brief, Defs.’ Mem. 64–65, enforcement procedures under the Rule will remain individualized and will begin with informal means. *See* 84 Fed. Reg. at 23,271, 23,222. Plaintiffs complain that large amounts of funding are “threatened.” NY Opp’n 43. But that is unchanged by the Rule—it is the Federal Conscience Statutes that determine which funds are covered by the conditions, and Plaintiffs do not challenge the Statutes. The Statutes themselves (or the 2011 Rule), moreover, contain even less detail about HHS’s enforcement procedures, making Plaintiffs’ assertion that they are entitled to a more iron-clad guarantee of the agency’s enforcement procedures especially hard to swallow. NY Opp’n 43–44.

Second, this is not the “dramatic[]” change at issue in *NFIB*, which the Supreme Court held was “a shift in kind, not merely degree.” *NFIB*, 567 U.S. at 583, 585. Plaintiffs have been subject to the Federal Conscience Statutes for decades. Plaintiffs argue that the Rule “redefines terms to include newly covered individuals, entities, and procedures.” NY Opp’n 43. As an initial matter, this assumes (wrongly) the success of Plaintiffs’ merits arguments that the Rule goes beyond simply implementing Congress’s instructions. In any event, Plaintiffs appear to believe that the Spending Clause requires that the federal government’s offer of funds be trapped in amber for

perpetuity. Not so. The Spending Clause does not bar all adjustments to the terms on which the federal government offers funds—if that were the case, the Supreme Court’s opinion in *NFIB* would likely have been much shorter. *See NFIB*, 567 U.S. at 575, 583, 585 (noting that “[t]here is no doubt that the Act dramatically increases state obligations under Medicaid” before engaging in multiple pages of Spending Clause analysis to determine the extent of the changes).

Finally, Plaintiffs describe at length the size of the pot of money which they believe could be affected by their potential noncompliance with the Statutes. NY Opp’n 43–46. But Plaintiffs do not even attempt to explain how the Rule would affect the size of this pot, because it would not. Congress has chosen which federal funds to link to anti-discrimination conditions. Thus Plaintiffs’ tacit admission that the Federal Conscience Statutes do not violate the Spending Clause is fatal—if Plaintiffs accept that the Weldon Amendment can condition all funds in the annual appropriations bill on compliance with its conditions, the Rule’s implementation of that instruction is not unconstitutionally coercive. And, of course, in their facial challenge, Plaintiffs must show that the Rule has no constitutional applications and cannot simply refer to the hypothetical and unprecedented possibility of HHS stripping large swaths of funding.

Finally, the Rule, like the Federal Conscience Statutes, is sufficiently related to the government’s interests. The New York Plaintiffs argue that the Rule, which clarifies how HHS will enforce the Federal Conscience Statutes as applied to funds that HHS administers will somehow affect Plaintiffs’ funds from the Departments of Labor and Education. NY Opp’n 46–47. But, as stated in Defendants’ opening brief, the Rule “applies only to HHS administered, conducted, or funded programs.” Defs.’ Mem. 67; *see also* 84 Fed. Reg. at 23,170 (“This final rule revises existing regulations to ensure vigorous enforcement of Federal conscience and anti-discrimination laws *applicable to the Department, its programs, and recipients of HHS funds*, and

to delegate overall enforcement and compliance responsibility to the Department’s Office for Civil Rights (‘OCR’).” (emphasis added)). To the extent that remedies under other regulations, such as the UAR, may affect other funds, those other regulations are not challenged by Plaintiffs.

VII. The Rule Does Not Violate the Establishment Clause.

Plaintiffs fail to successfully grapple with the tension between their insistence that the Rule somehow violates the Establishment Clause and their apparent concession that the Federal Conscience Statutes do not. Plaintiffs devote a single paragraph at the end of their argument to this issue. There, they acknowledge, as they must, that “[p]rohibiting discrimination on the basis of religion does not, in itself, violate the Establishment Clause.” PP Opp’n 44. They then state that religious accommodations should not abridge the religious liberties of others, PP Opp’n 44—an odd non-sequitur, given that Defendants have never understood Plaintiffs to argue that their religious beliefs require them to violate the Rule by discriminating against health care entities. Finally, Plaintiffs reach the meat of their argument when they claim that there is daylight between the Federal Conscience Statutes and the Rule in one respect for Establishment Clause purposes—according to Plaintiffs, the Rule’s definition of “discriminate” creates an “absolute duty” to accommodate objections that is absent in the Federal Conscience Statutes themselves and this duty violates the Establishment Clause. *See* PP Opp’n 44 (citing PP Opp’n Part II.A.1). But, as explained above, the Rule’s definition of “discriminate” is consistent with (and expressly limited by) the Federal Conscience Statutes. Plaintiffs have not shown that the Federal Conscience Statutes create a duty to accommodate that is any less “absolute” than the Rule. *Cf. Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 311 (9th Cir. 1974) (concluding that a provision of the Church Amendments satisfied the Establishment Clause without considering whether it created an “absolute” duty to accommodate religious objections). And Plaintiffs do not identify any language in any of the Federal Conscience Statutes that waters down the protections they provide.

Further, for all of the reasons why the *Statutes* do not violate the Establishment Clause, which Plaintiffs do not dispute, the *Rule* does not violate the Establishment Clause. *See Chrisman*, 506 F.2d at 311 (holding that a provision of the Church Amendments was lawful under the Establishment Clause); *Kong v. Scully*, 341 F.3d 1132 (9th Cir. 2003), *opinion amended on denial of reh'g*, 357 F.3d 895 (9th Cir. 2004) (upholding amendments to 42 U.S.C. §§ 1320 and 1395).

Like the Federal Conscience Statutes, the Rule is generally neutral between religion and non-religion. *See, e.g.*, 42 U.S.C. § 238n (Coats-Snowe Amendment); Pub. L. No. 115-245, Div. B., sec. 507(d), 132 Stat. 2981 (Weldon Amendment); 42 U.S.C. § 300a-7 (Church Amendments). Indeed, the Church Amendments, and thus the Rule in implementing them, equally protect entities from discrimination based on choosing *to* perform abortions and choosing *not to* perform abortions, whether the choice is based on religious or non-religious convictions. *See, e.g.*, 42 U.S.C. § 300a-7(c)(1). Indeed, the Rule's definition of "discriminate" (Plaintiffs' focus) is not a definition of "religious beliefs," but only applies to religious beliefs where the underlying statutes do. The fact that the government provides accommodations for both religious and non-religious objections has long been a factor indicating that there is no Establishment Clause violation, *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 704 (1994) (collecting cases), and Plaintiffs cite no contrary case law finding an Establishment Clause violation as to a statute or regulation that accommodates objections whether based on religion or not.

Indeed, contrary to Plaintiffs' argument that *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985), was primarily about absoluteness, the law at issue in *Thornton* was improper because it offered a benefit only to the religiously inclined. In *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 11 (1989), the Supreme Court upheld a property tax exemption that applied to religious and nonreligious organizations alike. Citing *Thornton*, the Court explained that "were [the] benefits

confined to religious organizations, they could not have appeared other than as state sponsorship of religion; if that were so, we would not have hesitated to strike them down for lacking a secular purpose and effect.” Similarly, in *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 144–46 (1987), the Supreme Court upheld the award of unemployment benefits to a religious objector. The Court considered *Thornton* as an example of an “unyielding weighting in favor of Sabbath observers over all other interests” that “ha[d] a primary effect that impermissibly advance[d] a particular religious practice.” *Id.* at 145 n.11 (quoting *Thornton*, 472 U.S. at 710 (alterations in *Hobbie*)). “In contrast, Florida’s provision of unemployment benefits to religious observers does not single out a particular class of such persons for favorable treatment and thereby have the effect of implicitly endorsing a particular religious belief. Rather, the provision of unemployment benefits generally available within the State to religious observers who must leave their employment due to an irreconcilable conflict between the demands of work and conscience neutrally accommodate[d] religious beliefs and practices, without endorsement.” *Id.* at 145 n.11.

Here, like in *Texas Monthly* and *Hobbie*, and unlike in *Thornton*, Plaintiffs do not dispute that most of the Federal Conscience Statutes address both religious and non-religious objections to certain services.⁸ *See* Defs.’ Mem. 69 (discussing, for example, the Weldon and Church Amendments). There is thus no Establishment Clause problem. *See Thornton*, 472 U.S. at 711 (O’Connor, J., concurring) (stating that the statute impermissibly “singles out Sabbath observers

⁸ And the handful of Federal Conscience Statutes that are limited to religious objectors, *see, e.g.*, 42 U.S.C. §§ 1320a-1(h) (referring to religious nonmedical health care institutions), are not challenged by Plaintiffs. In any event, the Establishment Clause does not prevent the government from accommodating religion. *See, e.g.*, *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 335 (1987).

for special . . . protection without according similar accommodation to ethical and religious beliefs and practices of other private employees”).

Plaintiffs’ selective objection to features of the Rule that merely reflect the underlying Federal Conscience Statutes is also apparent in Plaintiffs’ argument that the Rule is improper because its text refers to religious liberty interests. PP Opp’n 43. But it is entirely permissible for the Rule to acknowledge that one of its objectives—but not the *only* objective—is the protection of religious freedom. *See, e.g.*, 84 Fed. Reg. at 23,170 (“The United States has a long history of providing protections in health care for individuals and entities on the basis of religious beliefs *or moral convictions.*” (emphasis added)). This language mirrors various underlying Statutes that also refer explicitly to the protection of religious conscience objections *and* to the protection of non-religious conscience objections. *See, e.g.*, 42 U.S.C. § 300a-7 (Church Amendments, hinging on a person’s “religious beliefs or moral convictions”). That Plaintiffs see this phrasing as a reason to object to the Rule—but not to the Statutes—underscores the incoherence of Plaintiffs’ attempts to separate the two.

On the matter of burden to third parties, Plaintiffs now concede that, as Defendants stated in their opening brief, the Establishment Clause does not flatly prohibit accommodations that may burden third parties, PP Opp’n 43—instead, the potential burden is one factor that the court considers to determine if an accommodation strays into the unlawful fostering of religion. *Cf. Chrisman*, 506 F.2d at 311 (concluding that a provision of the Church Amendments satisfied the Establishment Clause without considering whether it burdened third parties). This is in keeping with Supreme Court precedent: “[In *Gillette*,] the Court upheld a military draft exemption, even though the burden on those without religious objection to war (the increased chance of being drafted and forced to risk one’s life in battle) was substantial. And in *Corporation of Presiding*

Bishop, the Court upheld the Title VII exemption even though it permitted employment discrimination against nonpractitioners of the religious organization’s faith.” *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist.*, 512 U.S. at 725. Here, of course, as previously discussed, the Rule does not improperly foster religion because it also applies to non-religious objections to the provision of certain services.

VIII. The Rule Does Not Create Separation of Powers Concerns.

Plaintiffs’ arguments concerning the separation of powers, NY Opp’n 38–39, misapprehend the Rule in several ways. First, Plaintiffs incorrectly suggest that the Rule differs from the Federal Conscience Statutes in terms of the amount of money or funding sources that could be affected. As previously explained, the Rule does not change the Statutes’ substantive requirements and thus does not newly link funds tied by statute to the Church Amendments (for example) to violations of the Weldon Amendment (for example) or *vice versa*. It is thus incorrect to say the Rule “allows HHS to withhold all of the federal funding that Plaintiffs receive from the Department based on any perceived violation of any of the underlying statutes.” NY Opp’n 38.

Second, Plaintiffs disingenuously suggest that the Weldon Amendment’s clear statement that “[n]one of the funds made available in this Act may be made available to [entities that engage in prohibited conduct]” is insufficient for HHS to act because it does not contain the word “HHS.” NY Opp’n 38–39; *see also* Pub. L. No. 115-245, Div. B, § 507(d), 132 Stat. 2981. Plaintiffs unsurprisingly offer no canon of construction supporting this perplexing interpretation, which would leave the Weldon Amendment—enacted by each Congress since 2004—as an empty rhetorical device that no federal agency has the power to obey.

IX. The Court May Not Consider Plaintiffs' Extra-Record Declarations In Assessing The Merits.

The Court should not consider Plaintiffs' declarations when assessing the merits of Plaintiffs' claims against the Rule, because review of such claims is limited to the administrative record before the agency—not extra-record materials first submitted in court such as the declarations provided by Plaintiffs. *See, e.g.*, NY Opp'n 44–45 nn.33–41 (citing declarations in Plaintiffs' Spending Clause argument); *id.* at 14–15 nn.4–5, 16, 17 n.9 (citing a declaration in support of Plaintiffs' argument that the Rule is arbitrary and capricious under the APA).

The APA provides that, “[i]n making the [] determinations [regarding the lawfulness of agency action], the court shall review the whole record,” 5 U.S.C. § 706, and the Supreme Court long ago held that the whole record means “the full administrative record that was before the Secretary at the time he made his decision,” *Citizens to Pres. Overton Park Inc. v. Volpe*, 401 U.S. 402, 420 (1971). The Supreme Court has reiterated this conclusion in subsequent decisions. In *Camp v. Pitts*, for example, the Court explained that “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” 411 U.S. 138, 142 (1973). And in *Florida Power & Light Co. v. Lorion*, 470 U.S. 729 (1985), the Court stated that “[t]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court.” *Id.* at 743–44; *see also Nat'l Audobon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (“Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision.”). To admit additional evidence that was never before agency decisionmakers is to invite the district court to conduct a prohibited *de*

novo review of the issue before the agency. *Sierra Club v. U.S. Army Corps of Eng’rs*, 772 F.2d 1043, 1052 (2d Cir. 1985).⁹

Plaintiffs’ constitutional claims, too, are governed by the APA—the APA provides the private right of action necessary for Plaintiffs to assert these claims for equitable relief with respect to final agency action. Defendants are aware of no statute other than the APA that would provide Plaintiffs with a private right of action to raise these constitutional claims, and Plaintiffs cite none. Multiple courts across the country have held that § 706 of the APA, by its plain language, restricts the review of constitutional claims to the administrative record. *See Chang v. United States Citizenship & Immigration Servs.*, 254 F. Supp. 3d 160, 161 (D.D.C. 2017); *see also Harkness v. Sec’y of Navy*, 858 F.3d 437, 451 n.9 (6th Cir. 2017) (explaining that a constitutional claim “is properly reviewed on the administrative record”), *cert. denied*, No. 17-955, 2018 WL 3013822 (June 18, 2018); *Jarita Mesa Livestock Grazing Ass’n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1232–33 (D.N.M. 2014); *Evans v. Salazar*, No. Co8-0372, 2010 WL 11565108, at *2 (W.D. Wash. July 7, 2010); *Harvard Pilgrim Health Care of New England v. Thompson*, 318 F. Supp. 2d 1, 10 (D.R.I. 2004); *Charlton Mem’l Hosp. v. Sullivan*, 816 F. Supp. 50, 51 (D. Mass. 1993). A contrary rule—one admitting of a special exception for constitutional claims—would “incentivize every unsuccessful party to agency action to allege . . . constitutional violations to trade in the APA’s restrictive procedures” for the Federal Rules of Civil Procedure. *Jarita Mesa Livestock Grazing Ass’n*, 58 F. Supp. 3d at 1238.

⁹ There are narrow exceptions permitting the consideration of extra-record in rare cases, *see, e.g., Nat’l Audubon Soc. v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997), but Plaintiffs do not assert that any of those exceptions apply here (and they do not).

X. Any Relief Accorded to Plaintiffs Should be Limited.

A. The Court Should Grant Relief Only As To Specific Portions of the Rule It Deems Unlawful, If Any.

For all the reasons described above, and in Defendants' opening brief, the Rule is lawful. Plaintiffs insist, however, that, if the Court finds that any part of the Rule is invalid, it must strike down the Rule in its entirety, rather than respect the agency's clear intent that portions of the Rule found to be invalid should be severed from the remainder. *See* NY Opp'n 54–55; *see also* 84 Fed. Reg. at 23,272. Plaintiffs fault Defendants for providing only a "skeletal suggestion" that this Court engage in a severability analysis. But Plaintiffs ignore that it is *Plaintiffs'* burden—not Defendants'—to explain why any portion of a lawfully promulgated regulation should not be allowed to go into effect. *Cf. Alaska Airlines v. Donovan*, 766 F.2d 1550, 1560 (D.C. Cir. 1985) ("[T]he burden is placed squarely on the party arguing against severability to demonstrate that Congress would not have enacted the provision without the severed portion."). It is therefore Plaintiffs whose severability analysis is lacking.

In any event, portions of the Rule can clearly operate independently from each other. For example, if the Court were to strike down any particular definition in the Rule (which it should not, for the reasons explained above), the remaining definitions and other provisions of the Rule could continue to operate independently. Plaintiffs have provided no reasoned basis for their insistence that the Rule must either survive or fall as a whole, where HHS has explicitly explained that it intended for the constituent parts to survive independently. *See* Defs.' Mem. 79–80.

B. Any Relief Should Not Extend Beyond the Parties Before the Court.

Again, although the Rule is lawful for the reasons Defendants have explained, if the Court were to disagree, any relief must be limited to the specific Plaintiffs before the Court. Plaintiffs insist that nationwide relief is the "usual" remedy under the APA. But Plaintiffs ignore the

Supreme Court's recent instruction to the contrary. In *Gill v. Whitford*, 138 S. Ct. 1916 (2018), the Court explained that any remedy "must be tailored to redress the plaintiff's particular injury." *Id.* at 1934. Even though the plaintiffs in this litigation include a number of states and organizations, vacating the Rule on a nationwide basis would go far beyond what is necessary to address these states' and organizations' particular alleged injury, violating established principles of equitable discretion. *See* Defs.' Mem. 77–78. And nationwide relief would effectively stop courts in other jurisdictions assessing similar challenges from evaluating those separate claims. *See id.* at 78.

C. Plaintiffs Concede that Any Relief Should Not Impact Any Investigations Based on the 2011 Rule or the Federal Conscience Statutes.

In their opening brief, Defendants explained that even if the Court were to strike down any or all of the Rule, the Court should make clear in its order that the relief does not prevent HHS from continuing to investigate violations of, and to enforce, federal conscience and anti-discrimination laws under the existing 2011 Rule or the Federal Conscience Statutes themselves. Plaintiffs have now confirmed that are not challenging the underlying Statutes on which the Rule is based, NY Opp'n 55, and therefore apparently concede that any relief should not limit HHS's existing statutory or regulatory enforcement authority.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion and deny Plaintiffs' motions.

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Respectfully submitted,

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